REMARKS/ARGUMENTS

Claims 2-15 and 17-29 remain in this application. Claims 6, 7, 9, 10, 15, 17-21, 23, and 27 have been amended.

Rejections under 35 U.S.C. § 101

The Examiner has rejected claims 23-25 under 35 U.S.C. § 101 as being directed to non-statutory subject matter.

In the absence of a more detailed explanation from the Examiner regarding her reasons for finding these claims to be drawn to non-statutory subject matter, Applicants are unable to respond fully to the rejection. To the extent, however, that this rejection is based on the dependency of claim 23 on cancelled claim 1, Applicants have amended claim 23 to depend on claim 10 and would suggest that this amendment would render the rejection moot. To the extent the rejection is based on something else, Applicants respectfully traverse this rejection.

Claims 23-25 are directed to a pharmaceutical package with various explicitly recited material components. As such, these claims are directed to articles of manufacture which are statutory under 35 U.S.C. § 101. The Examiner is respectfully requested to withdraw these rejections under 35 U.S.C. § 101.

Rejections under 35 U.S.C. § 112

The Examiner has rejected claims 2-15 and 17-29 under 35 U.S.C. § 112, second paragraph.

Regarding claim 10, the Examiner states that the term "other" renders the claim and all other claims ultimately dependent on it indefinite. Applicant's disagree with the Examiner that the use of the phrase "and optionally other pharmaceutically acceptable excipients" renders the claims indefinite. The claim elements in view of the "comprises" language are open-ended and therefore optionally contain other, non-specified ingredients, so the quoted language is at worst, redundant. Applicants have removed the redundant language without changing in any way the scope of the claim and request the Examiner withdraw the rejection under 35 U.S.C. § 112, second paragraph.

The Examiner correctly points out that claims 19 and 23 depended on cancelled claim 1. Applicants have amended these claims to correct the dependency so they now depend

PAGE 8/12 * RCVD AT 5/19/2004 11:18:11 AM [Eastern Daylight Time] * SVR:USPTO-EFXRF-1/1 * DNIS:8729306 * CSID:7325242808 * DURATION (mm-ss):06-18

from claim 10 and request the Examiner to withdraw her rejection under 35 U.S.C. § 112, second paragraph.

The Examiner has stated that the parenthetical "(avoiding)" in claim 27 is unclear. At the examiner's request, Applicants have amended this claim to recite "or avoiding" and request the Examiner to withdraw her rejection under 35 U.S.C. § 112, second paragraph.

The Examiner has stated that the use of "HPMC 2910 5 mPa. s." in claims 6 and 7 is unclear. Applicants point out that this language is fully explicated in the specification at page 4, lines 17-24. Without changing the scope of the claims in any way, Applicants have amended the claims to insert "with an apparent viscosity of" and "when dissolved in a 2 % aqueous solution at 20°C" in the claim and request the Examiner to withdraw her rejection under 35 U.S.C. § 112, second paragraph.

The Examiner has stated that claims 9 and 15 refer to literature citations. Applicants have amended these claims to remove the literature citations and request the Examiner to withdraw her rejection under 35 U.S.C. § 112, second paragraph.

Claim Objections

The Examiner has objected to claims 12, 17-19, 21 and 22 under 35 C.F.R. § 1.175(c) as being in improper multiple dependent form. Applicants have amended these claims to remove the improper forms, by referring to all other claims in the alternative and by incorporating the intermediate limitations from the claims that are themselves multiply dependent. Applicants respectfully request that the Examiner withdraw her objections to these claims.

Rejections under 35 U.S.C. § 102

The Examiner has rejected claims 2-6, 10, 17, 22, 23 and 25 under 35 U.S.C. § 102 as being anticipated by Davis et al. (CA 1326632).

The Examiner states that Davis discloses a formulation that contains particles coated with a pharmaceutically acceptable substance that is soluble in the intestinal tract and that are sieved and mixed with various excipients and that are coated with a distributions of coating thickness to ensure the release of drug particles at different rates.

The Examiner then states that Davis discloses a long-acting Galanthamine formulation for treating Alzheimer's disease and related dementias but is silent on administration specifically to a human subject but that such a subject is implied in the

PAGE 9/12 * RCVD AT 5/19/2004 11:18:11 AM [Eastern Daylight Time] * SVR:USPTO-EFXRF-1/1 * DNIS:8729306 * CSID:7325242808 * DURATION (mm-ss):06-18

disclosure. The Examiner also states that the polyvinylpyrrolidone is a film-forming polymer.

Applicants respectfully traverse this rejection.

The standard for anticipation unquestionably is one of strict identity between the claimed invention and the prior art. See *Glaverbel Societe Anonyme v. Northlake Mktg. & Supply, Inc.*, 45 F.3d 1550, 1554 (Fed. Cir. 1995); see also *Titanium Metals Corp. of Am. v. Banner*, 778 F.2d 775, 780 (Fed. Cir. 1985) ("anticipation under § 102 can be found only when the reference discloses exactly what is claimed"); *Saf-Gard Prods., Inc. v. Service Parts, Inc.*, 532 F.2d 1266, 1270 (9th Cir. 1976) (Kennedy, J.) ("Anticipation is strictly a technical defense. Unless all of the same elements are found in exactly the same situation and united in the same way to perform the identical function in a single prior art reference there is no anticipation." (citations and internal quotation marks omitted)).

Applicants note that, in her rejection, the Examiner has not addressed a limitation of the presently-claimed invention: the release rate controlling membrane coating comprising a water insoluble polymer found in claim 10 from which all claims ultimately depend.

Davis (CA 1326632) in fact teaches a formulation using a water-soluble polymer, polyvinylpyrrolidone, as a coating agent, rather than a water-insoluble polymer (see paragraphs 5 and 6 of the Davis (CA 1326632) specification). That polyvinylpyrrolidone is a water-soluble polymer is called out specifically in the present application at page 14 lines 14-37 and claim 5 (as filed and as currently pending). Nothing in Davis (CA 1326632) teaches or suggests a release rate controlling membrane coating comprising a water insoluble polymer. The only mention of other excipients such as hydroxypropyl methyl cellulose, ethyl cellulose, starch and like is in paragraph 6 where Davis (CA 1326632) specifically teaches mixing the granules with these excipients to form tablets or to be incorporated in a capsule; these excipients are not used and there is no suggestion to use them as a membrane, let alone as a release-rate controlling membrane.

Absent a teaching in Davis (CA 1326632) of a release rate controlling membrane coating comprising a water insoluble polymer, there is no strict identity between that reference and the present invention. Absent that identity, there is no anticipation. Applicants therefore respectfully request the Examiner to withdraw her rejections under 35 U.S.C. § 102.

PAGE 10/12 * RCVD AT 5/19/2004 11:18:11 AM [Eastern Daylight Time] * SVR:USPTO-EFXRF-1/1 * DNIS:8729306 * CSID:7325242808 * DURATION (mm-ss):06-18

Rejections under 35 U.S.C. § 103

The Examiner has rejected claims 7, 24, 25, and 27-29 under 35 U.S.C. 103(a) as being unpatentable over Davis (CA 1326632) in view of United States Patent No. 4,663,318 to Davis (hereinafter, "Davis '318").

The Examiner states that Davis '318 teaches a galanthamine formulation and implies administering that formulation to a patient in need thereof. The Examiner also states with regard to claims 7, 24 and 25 that formulating a galanthamine formulation to release the active agent for treatment of the disease is within the purview of a person of ordinary skill and that it is not inventive to discover optimal workable ranges by routine experimentation. With regard to claim 28, the Examiner states that the formulation of the prior art would be expected to be effective against conditions related to Alzheimer's disease. The Examiner finally states that the adverse effects recited in claim 29 are inherent effects associated with acetylcholine esterase inhibitors. From these statements, the Examiner concludes that it would have been obvious to one of ordinary skill in the art at the time of the present invention to "prepare a galanthamine formulation according to the teachings of Davis [and that o]ne having ordinary skill in the art would have been motivated to administer the galanthamine formulation of Davis to a subject in need thereof according to the teaching of Davis . . . ."

Applicants respectfully traverse these rejections and suggest that the Examiner has failed to establish a *prima facie* case of obviousness. In order to establish such a case, the Examiner must show that all the claim limitations are taught or suggested by the prior art cited. MPEP § 2143.03 (citing, *inter alia*, *In re Royka*, 409 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (CCPA 1970)). The two Davis references relied upon by the Examiner fail to teach or suggest, and nowhere in the Examiner's Detailed Action is there mention of, the release rate controlling membrane coating comprising a water insoluble polymer. This release rate controlling membrane coating comprising a water insoluble polymer is present in all of the claims now before the Examiner. Absent a teaching or suggestion of such a coating, there is no *prima facie* case of obviousness. Applicants respectfully request that the Examiner withdraw her rejections under 35 U.S.C. 103(a).

Conclusion

For all of the reasons above, claims 2-15 and 17- 29 are believed to be in condition for allowance, early notice of which would be appreciated. If the Examiner does not agree that all claims are allowable, then Applicants request an interview (either by telephone or in-

PAGE 11/12 * RCVD AT 5/19/2004 11:18:11 AM [Eastern Daylight Time] * SVR:USPTO-EFXRF-1/1 * DNIS:8729306 * CSID:7325242808 * DURATION (mm-ss):06-18

person) between the Examiner and Applicants' representative to discuss any remaining issues.

A fee of $162 for added claims as set forth on the accompanying transmittal sheet is believed to be due with this response. Authorization is hereby given to charge all required fees or to credit overpayment of fees to Johnson & Johnson Deposit Account No. 10-0750/JAB 1461/MBZ.

Respectfully submitted,

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PAGE 12/12 * RCVD AT 5/19/2004 11:18:11 AM [Eastern Daylight Time] * SVR:USPTO-EFXRF-1/1 * DNIS:8729306 * CSID:7325242808 * DURATION (mm-ss):06-18